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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/347,845 | 09/30/1999 | YI YANG | 243/079 | 4401 |

7590 08/09/2002
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EXAMINER

BUI, VY Q

| | |
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| ART UNIT | PAPER NUMBER |
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3731

DATE MAILED: 08/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/347,845

Applicant(s)

YANG ET AL.

Examiner

Vy Q. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-15 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-15 and 17-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites the limitation "the "V" shaped curved wing regions". However, there is no positive antecedent basis for this limitation in the claim. Claim 18 recites the limitation "the apices all". As best understood, the recitation "the apices all" means "all the apices of the "V" shaped curved wing regions". However, there is no positive antecedent basis for the limitation in the claim.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1, 3-4, 8-15, 17-22 and 24-25 are rejected under 35 U.S.C. 102(e) as being anticipated by VON OEPEN (6,193,747).

As to claims 1, 3-4, 8-11, and 24-25, VON OEPEN (Fig. 8 as copied and shown below; column 1, lines 36-39) discloses a zigzag pattern tubular stent (60) expandable from a contracted condition for easy introduction of the stent into a body lumen (a blood vessel) to an enlarged condition for supporting and keeping the body lumen (the blood vessel) open. Inherently, the stent is biased towards enlarged condition from a contracted condition (as recited in claims 4, 24-25) to support the body lumen. The stent comprises:

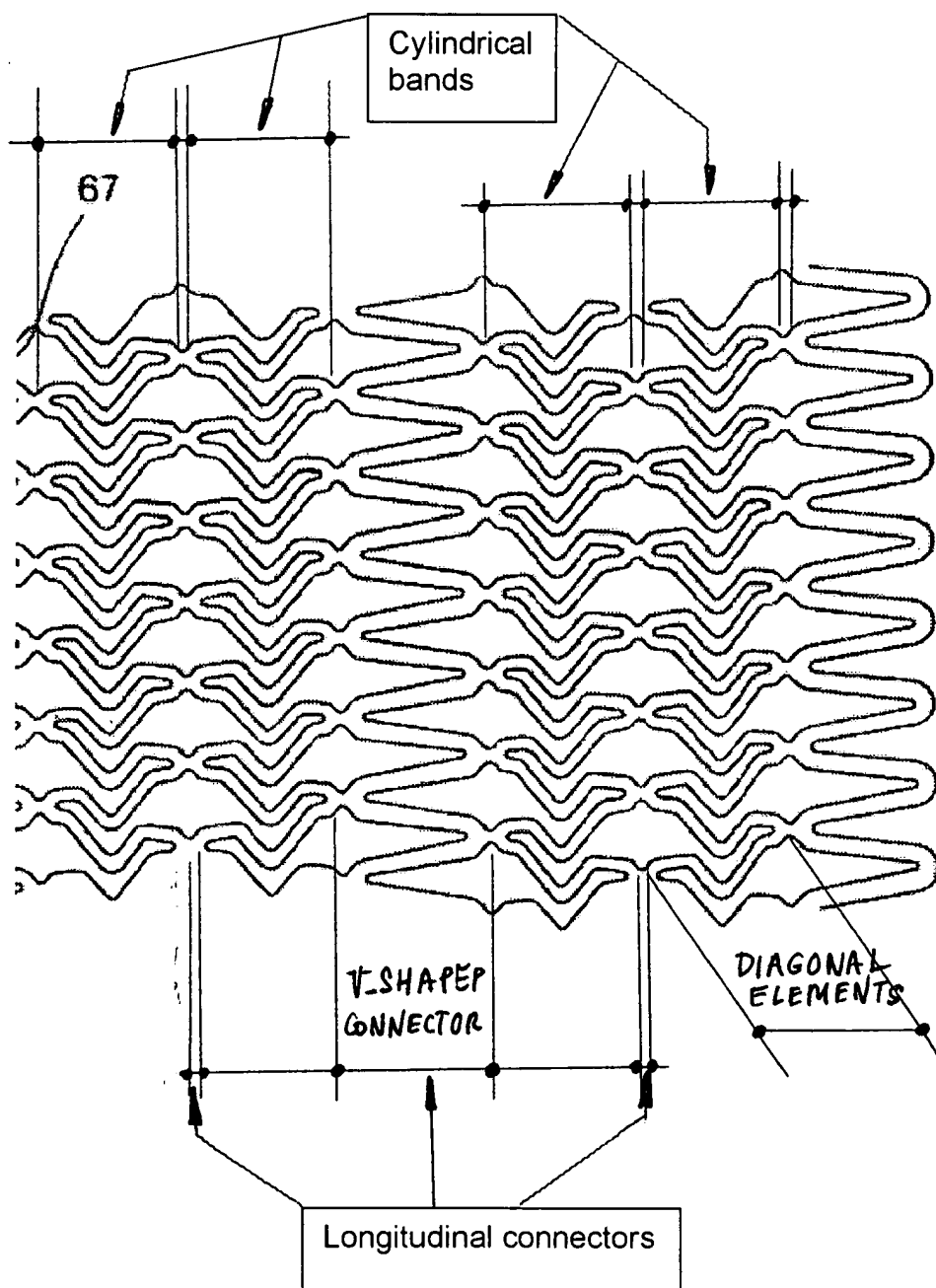
- A plurality of cylindrical bands of diagonal elements having generally arcuate shapes, arbitrarily assigned either a clockwise or counter clockwise orientation.
- A plurality of longitudinal connectors (I-shaped and V-shaped) extending substantially parallel to the longitudinal axis of the stent.
- The longitudinal connectors have a longitudinal dimension substantially smaller than a longitudinal dimension of the diagonal elements (as recited in claim 9).

The diagonal elements comprise 1st and 2nd generally straight portions having 1st

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ends connected to preceding and succeeding diagonal elements and 2nd ends being connected together (as recited in claim 10).

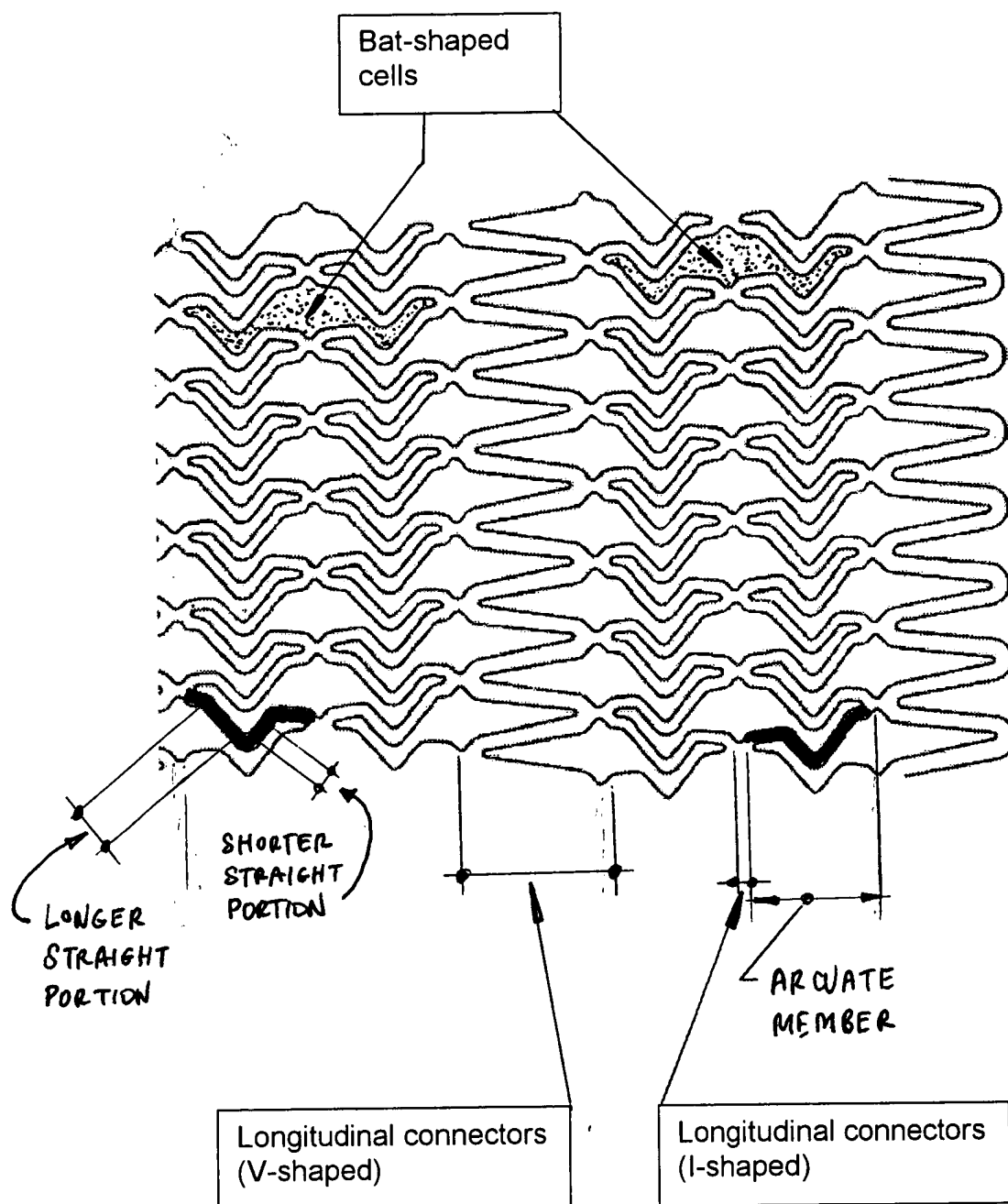
- The diagonal elements of each cylindrical band are out of phase with any adjacent cylindrical band (as recited in claim 11).



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As to claims 12-15 and 17-22, VON OEPEN (Fig. 8 as copied and shown below; column 1, lines 36-39) discloses a tubular stent (60) comprising:

- Bat-shaped cells each having a head region, a tail region, opposing curved wing regions.
- Connectors (I-shaped or V-shaped) extending substantially parallel to a longitudinal axis (as recited in claims 12 and 15).
- The head and tail regions are aligned about the circumference of the stent, the wing regions have a generally V-shaped extending longitudinally away from the head and tail regions (as recited in claim 13).
- The cells are arranged sequentially about the circumference, thereby defining a cylindrical band (as recited in claim 14).
- The wing regions are defined by 1st and 2nd arcuate members, the 1st and 2nd arcuate members comprising a pair of generally straight portions connected to one another by a curved portion, and the curved portion defines an apex of the "V" shape curved wing regions, the apices all pointing substantially in a single direction (as recited in claims 17-18).
- The head regions and tail regions are defined by longitudinal connectors (I-shaped connectors), one of the straight portions of each of the first and second arcuate members is substantially shorter than the other generally straight portion of the respective arcuate member, and the longitudinal connectors define the tail region also define the head region of an adjacent cell (as recited in claims 19-21).
- The connectors comprise a longitudinal connector (V-shaped connector) extending between a wing region of a first cell and a wing region of an adjacent cell (as recited in claim 22).



Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 2 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over VON OEPEN (6,193,747) in view of STEINKE (6,224,626).

As to claims 2 and 23, VON OEPEN discloses substantially all structural limitations as recited in the claims, except for the stent 60 is not a coiled-sheet stent. STEINKE (column 2, lines 15-19; claim 6) discloses a coiled sheet stent of a shape memory material such as Nitinol having a variable expanded diameter to better fit inside a blood vessel over a tubular stent, which generally has a fixed expanded diameter when deployed in a blood vessel. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make VON OEPEN stent 60 a coiled-sheet stent as claimed as this configuration would provide a stent with variable expanded diameter to better fit inside a blood vessel.

3. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over VON OEPEN (6,193,747) in view of STEINKE (6,224,626) and further in view of KHOSRAVI et al (5,824,054).

As to claims 5-6, VON OEPEN (Figs. 8-9, 4-6) discloses substantially all structural limitations as recited in the claims, including ends of adjacent diagonal are expanded further away from one another in a stretched condition than in an unstretched condition. VON OEPEN and STEINKE do not disclose the stent made of a shape memory alloy having a transition temperature below the body temperature. However, KHOSRAVI (column 5, lines 59-63) discloses a coiled sheet stent made of a shape memory alloy having a transition temperature below body temperature. It would have been obvious to

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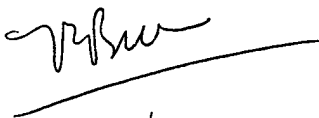
one of ordinary skill in the art at the time the invention was made to make the VON OEPEN stent a coiled-sheet stent of a shape memory alloy having a transition temperature below body temperature as taught by KHOSRAVI, as this modification would allow the stent to be expanded by the body temperature of a patient when deployed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-2708 for regular communications and 703-308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



VQB VB

August 6, 2002.